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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,919	08/26/2003	Paul Joseph Dominowski	15634 (PC25246)	2440

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SCULLY SCOTT MURPHY & PRESSER, PC
400 GARDEN CITY PLAZA
SUITE 300
GARDEN CITY, NY 11530

EXAMINER	
HURT, SHARON L	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,919	DOMINOWSKI, PAUL JOSEPH	
	Examiner	Art Unit	
	Sharon Hurt	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a).. In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *12-19 and 32-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,20-31 and 76-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Response to Remarks

Applicant elected Group I, claims 1-11, 20-31 and 76-83, and species election of *Leptospira borgpetersenii hardjo-bovis* in the reply filed April 20, 2006. Claims 8-11, 28-31 and 80-82 were withdrawn from consideration because they are drawn to a non-elected species.

Response to Amendment

Applicant's amendments to the claims filed August 30, 2006 are acknowledged. Claims 1-2, 4-11, 20-31 and 76-83 are currently amended. Claims 12-19 and 32-75 are withdrawn without prejudice. Claims 1-11, 20-31 and 76-83 are pending and under examination in light of applicant's amendments.

Response to Arguments

Rejections Withdrawn

The rejection of Claims 5-6, 25-26 and 79 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the claims contain a trademark/trade name product has been **withdrawn** pursuant applicant's amendments.

Applicant's arguments, see page 11, with respect to the rejection of claims 1-2, 7, 20-21, 27 and 76 under 35 U.S.C. 102(b) as being anticipated by Talens et al. of record have been fully

considered and are persuasive. The rejection of claims 1-2, 7, 20-21, 27 and 76 has been **withdrawn**.

Rejections Maintained

The rejection of claims 1-2, 7, 20-21, 27, 76 and newly amended claims 8-11, 28-31 and 80-82 under 35 U.S.C. 102(b) as being anticipated by Bowland et al. of record is **maintained**. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that Bowland does not disclose inactivated virus of BVDV types 1 and 2. The commercial vaccine BoviSheild™3 referenced in Table 1 (page 35) contains BVDV Type 1 and BDVD Type 2. Therefore Bowland does teach the instant claimed invention.

The rejection of claims 1-7, 20-27, 76-79, 83 and newly amended claims 8-11, 28-31 and 80-82 under 35 U.S.C. 103(a) as being unpatentable over Talens et al. **or** Bowland et al. as applied to claims 1-2, 7, 20-21, 27 and 76 above, and further in view of Barr et al., Pruette et al. and Wilson et al. of record is **maintained**. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that neither Talens nor Bowland teach an immunogenic composition or a vaccine comprising BHV-1, PI3, BRSV, an adjuvant, BVDV-1, BVDV-2 and a carrier. Bowland teaches about vaccines with infectious bovine rhinotrachetitis virus (IBRV), bovine herpes-1 (BHV-1), bovine respiratory syncytial virus (BRSV), parainfluenza-3 virus (PI-3), and bacterial antigens including Leptospira serovars (page 33 and Table 1, pages 43-45). As stated

above BoviSheild™3 referenced in Table 1 (page 35) contains BVDV Type 1 and BDVD Type 2.

Applicant also argues that the present invention as stated in the specification offers a higher level of protection. Applicant is arguing features that are not in the instant claimed invention. The claimed invention is drawn to a vaccine composition comprising BHV-1, PI-3, BRVS, BVDV-1, BVDV-2, a carrier/adjuvant and a bacterial antigen (*Leptospira borgpetersenii hardjo-bovis).* The claimed invention is not drawn to a higher level of protection.

Applicant further argues "the available vaccines are not indicated for use in pregnant cattle or calves nursing pregnant cows". Some of the commercial vaccines available as referenced in Bowland, listed in Table 1 (pages 37-39) include BVDV and are recommended for use in pregnant cows, including lactating cows (page 38). However, the claimed invention is not drawn to a vaccine that is indicated for use in pregnant cattle or calves nursing pregnant cows. Applicant is arguing about limitations that are not in the claimed invention.

Applicant argues that Barr teaches away from using Quil A adjuvants in the compositions of the present invention. To the contrary, Barr teaches that Quil A is routinely used in veterinary vaccines (page 249, top of 1st column).

Applicant argues that Pruett does not suggest that the adjuvants used in the vaccine could be used successfully in the composition of the present invention. Pruett does suggest that this mixture would be worthy of further efficacy investigation in a vaccine formulation (page 143, Abstract). The motivation is of record. Applicant further argues that Pruett provides conflicting teachings and "teaches away from using these adjuvants in the compositions of the present invention". In response to applicant's arguments against the references individually, one cannot

show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The relevant teaching is found where Pruette teaches that alhydrogel and amphigen (a mineral oil-based adjuvant) induced the highest serum antibody response (page 143 and Abstract)

Applicant argues that Wilson does not suggest that the adjuvants used in the swine vaccine could be used successfully in the compositions of the present invention. Wilson teaches about trials showing that adjuvants containing mineral oil induce better protection than aluminum hydroxide (page 299, 2nd column). Applicant further argues "there is no indication in Wilson that would suggest that the reference be combined with other cited references". In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The relevant teaching is found in Wilson who teaches about a comparison of a variety of vaccine adjuvants including vegetable oil, mineral oil, aluminum hydroxide, polyethylene glycol, Quil A and Amphigen (page 299, 1st column). The trials indicated that the mineral oil adjuvant induced better protection (page 299, 2nd column).

Applicant argues "there is no indication in any of the references that would suggest they be combined, and thus there can be no reasonable expectation of success". Bowland teaches the vaccine compositions and intended use of the multi-vaccines. Barr teaches about adjuvants and the use of Quil A in veterinary compositions. Pruett suggests the use of theses adjuvants in

vaccine compositions. Wilson teaches that mineral oil adjuvants induce better protection. Therefore, the motivation and expectations of reasonable success are taught in the cited references.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

December 13, 2006

Brenda Brumback

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600